## **Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1-3 (canceled)

Claim 4 (previously presented) A formulation according to claim 10 wherein the water soluble film forming polymer is a polymer that has an apparent viscosity of 1 to 100 mPa.s when dissolved in a 2 % aqueous solution at 20°C solution.

Claim 5 (previously presented) A formulation according to claim 4 wherein the water soluble polymer is selected from the group consisting of

- alkylcelluloses such as methylcellulose,
- hydroxyalkylcelluloses such as hydroxymethylcellulose, hydroxyethylcellulose,
- hydroxypropylcellulose and hydroxybutylcellulose,
- hydroxyalkyl alkylcelluloses such as hydroxyethyl methylcellulose and hydroxypropyl methylcellulose,
- carboxyalkylcelluloses such as carboxymethylcellulose,
- alkali metal salts of carboxyalkylcelluloses such as sodium carboxymethylcellulose,
- carboxyalkylalkylcelluloses such as carboxymethylethylcellulose,
- carboxyalkylcellulose esters,
- starches,
- pectines such as sodium carboxymethylamylopectine,
- chitine derivates such as chitosan,
- polysaccharides such as alginic acid, alkali metal and ammonium salts thereof, carrageenans, galactomannans, traganth, agar-agar, gummi arabicum, guar gummi and xanthan gummi,
- polyacrylic acids and the salts thereof,
- polymethacrylic acids and the salts thereof, methacrylate copolymers,
- polyvinylalcohol,
- polyvinylpyrrolidone, copolymers of polyvinylpyrrolidone with vinyl acetate
- polyalkylene oxides such as polyethylene oxide and polypropylene oxide and copolymers of ethylene oxide and propylene oxide.

Claim 6 (previously presented) A formulation according to claim 5 wherein the water soluble polymer is hydroxypropyl methylcellulose HPMC 2910 with an apparent viscosity of 5 mPa.s when dissolved in a 2 % aqueous solution at 20°C.

Claim 7 (previously presented) A formulation according to claim 6 wherein the weight-byweight ratio of said hydroxypropyl methylcellulose to galantamine is in the range of 17: 1 to 1:5.

Claim 8 (canceled)

Claim 9 (previously presented) A formulation according to claim 10 wherein the inert spheres are 16-60 mesh  $(1,180-250 \mu m)$  sugar spheres.

Claim 10 (currently amended) A controlled release formulation containing galantamine as the active ingredient, characterized in that it comprises particles comprising galantamine hydrobromide (1:1), and a water soluble film forming polymer wherein the galantamine hydrobromide (1:1) and the water soluble film forming polymer are layered or coated on inert spheres, said particles being coated by a release rate controlling membrane coating wherein the release rate controlling membrane coating comprises a water insoluble polymer and optionally a plasticizer, and wherein the formulation further comprises a topcoat comprising galantamine and water-soluble polymer and wherein the formulation is capable of releasing in USP buffer pH 6.8 at 37°C in a paddle apparatus operating at 50 rpm, from 20 to 40 % of the total amount of galantamine.HBr in 1 hour, and more than 80 % of the total amount of galantamine.HBr in 10 hours.

Claim 11 (currently amended) A formulation according to claim 10 wherein the water insoluble polymer is ethylcellulose and the plasticizer is selected from the group emprising consisting of dibutyl sebacate, diethyl phthalate and triethyl citrate.

Claim 12 (original) A formulation according to claim 11 wherein the weight of the release rate controlling membrane coating ranges from 3 % to 15 % of the uncoated particle.

Claim 13 (previously presented) A formulation according to claim 10 wherein a seal coat lies between the drug core and the release rate controlling membrane coating.

Claim 14 (canceled)

Claim 15 (canceled)

Claim 16 (canceled)

- Claim 17 (currently amended) A <u>formulationdosage form</u> according to any of claims-4, 5, 6, 7, 9 or 13 which delivers a therapeutically effective amount of galantamine to a patient during the 24 hours following a single once daily administration.
- Claim 18 (currently amended) A <u>formulationdosage form</u> according to any of claims 4, 5, 6, 7, 9 or 13 wherein part of the galantamine is present in an immediate release form.

Claims 19 (canceled)

- Claim 20 (currently amended) A <u>formulationdosage form</u> according to <u>claim</u> 3018 wherein part of the galantamine is present in an immediate release form and said immediate release form comprises immediate release minitablets.
- Claim 21 (currently amended) A <u>formulation</u>dosage form according to claim 3018 wherein part of the galantamine is present in an immediate release form, said immediate release form further comprising a topcoat comprising galantamine and water-soluble polymer.
- Claim 22 (currently amended) A <u>formulationdosage form</u> according to claim 10 providing a mean maximum plasma concentration of galantamine from 10 to 60 ng/ml and a mean minimum plasma concentration from 3 to 15 ng/ml after repeated administration every day through steady-state conditions.

Claims 23-25 (canceled)

- Claim 26 (currently amended) A process of preparing a formulation according to claim 10 comprising admixing galantamine hydrobromide (1:1) with a water soluble film forming polymer and coating onto inert spheres to form a drug core, optionally applying a seal coat to the drug core, and thereafter applying the release rate controlling membrane coating, and thereafter applying a topcoat comprising galantamine and a water-soluble polymer.
- Claim 27 (previously presented) A method of treating Alzheimer's dementia and related dementias in a human while substantially reducing or avoiding the concomitant liability of adverse effects associated with acetyl cholinesterase inhibitors, comprising administering to a human in need of such treatment, a therapeutically effective amount of galantamine in a controlled release formulation as claimed in claim 10, said amount being sufficient to alleviate said Alzheimer's dementia and related dementias, but insufficient to cause said adverse effects.

- Claim 28 (currently amended) A method according to claim 27 wherein the related dementia belongs to the group consisting of vascular dementia, Lewy body disease, autism, mental retardation, bipolar disorder psychiatric conditions, disruptive behaviour, attention deficit, hyperactivity disorder, substance abuse, <u>and extreme aggression</u>, especially conduct disorder, nicotine cessation and withdrawal.
- Claim 29 (original) A method according to claim 27 wherein the adverse effects belong to the group comprising nausea, vomiting, sweating, restlessness, and insomnia.
- Claim 30 (previously presented) A formulation according to claim 10, wherein the particles are filled in a hard-gelatin capsule.